



ANALYSENZERTIFIKAT CERTIFICATE OF ANALYSIS

DQxUT0.02

Alt.20

8UT01C0.01

TECHNOZYM® ADAMTS-13 Activity Calibrator Set 6 x 0.5 mL

REF 5450761
LOT 8UT01C0.01
⌚ 2021-06-30

Inhalt Content	Volumen volume	Reagenz Reagent	LOT	⌚
1x	0.5mL	ADAMTS-13 Activity Calibrator 1	1UT92B0	2021-06-30
1x	0.5mL	ADAMTS-13 Activity Calibrator 2	2UT92B0	2021-06-30
1x	0.5mL	ADAMTS-13 Activity Calibrator 3	3UT92B0	2021-06-30
1x	0.5mL	ADAMTS-13 Activity Calibrator 4	4UT92B0	2021-06-30
1x	0.5mL	ADAMTS-13 Activity Calibrator 5	5UT92B0	2021-06-30
1x	0.5mL	ADAMTS-13 Activity Calibrator 6	6UT92B0	2021-06-30

Analytische Verfahren Analytical Procedures		Anforderung Requirement	Ergebnis Result	
visuelle Kontrolle visual inspection	Content	according to packaging SOP	confirmed	OK
	Vial label	according to packaging SOP	confirmed	OK
	Vial barcode	according to packaging SOP	confirmed	OK
	Box label	according to packaging SOP	confirmed	OK
	Box barcode	according to packaging SOP	confirmed	OK
	Package insert	present	confirmed	OK
	Batch table	present	confirmed	OK
Verwendbarkeit Usability	deltaOD Ca11-Ca16	≥ 0.7	1.7	OK
Kontrollwiederfindung Recovery of controls	ADAMTS-13 Activity High Control LOT RUY92B0	0.49 - 0.81 IU/mL	0.67 IU/mL	OK
	ADAMTS-13 Activity Low Control LOT RUZ92B0	0.14 - 0.32 IU/mL	0.23 IU/mL	OK

Durchgeführt von
Prepared by

Fikret NASUFI *Fikret Nasufi*

21. JAN. 2020

Datum / Date:

Freigabe von
Approved by

Michael KAFKA *[Signature]*

21. JAN. 2020

Datum / Date: